

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 610

[Docket No. 1980N-0208]

Display Date 12-23-04 @ 11:16 a.m.  
Publication Date 12-29-04  
Docket R LEPSMA

**Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Withdrawal**

12-27-04

REVISION

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule and final order; withdrawal.

**SUMMARY:** The Food and Drug Administration (FDA) published in the **Federal Register** of January 5, 2004 (69 FR 255), a final rule and final order (January 2004 final rule and final order) amending the biologics regulations in response to the report and recommendations of the Panel on Review of Bacterial Vaccines and Toxoids with Standards of Potency. On January 8, 2004 (69 FR 1320), a correction document was published to correct the effective date from "January 4, 2003", to "January 4, 2005." On February 13, 2004 (69 FR 7114), FDA issued a correction document to correct typographical errors in the reference section of the January 2004 final rule and final order.

On October 27, 2004, the United States District Court for the District of Columbia (the Court) issued a memorandum opinion vacating and remanding the January 2004 final rule and final order to FDA for reconsideration, following an appropriate notice and comment period. Because the January 2004 final rule and final order were <sup>vacated</sup> rendered void by the Court and to comply with the procedures of the **Federal Register**, FDA is withdrawing the January 2004 final rule and final order.

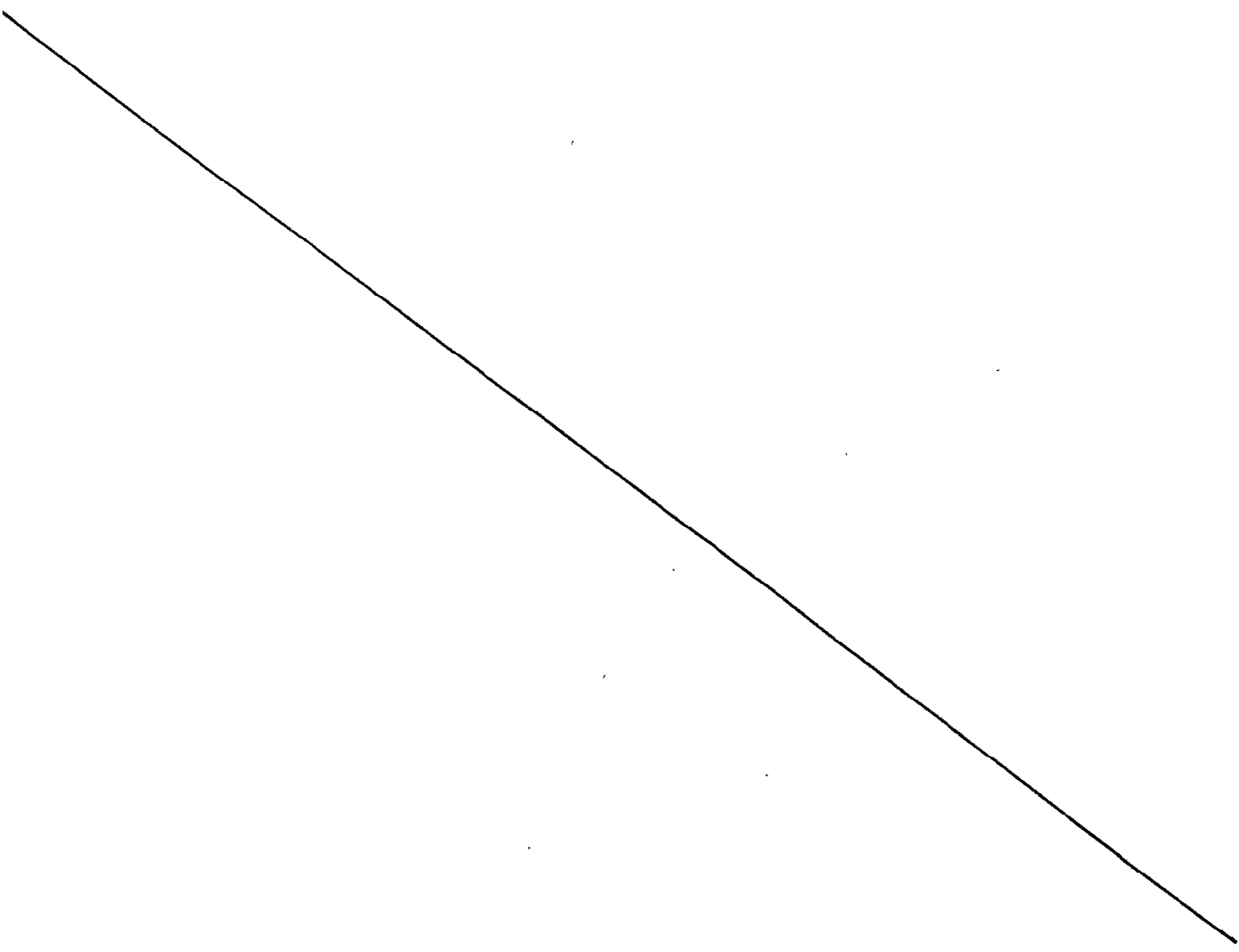
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In a proposed rule and proposed order published concurrently with this document, FDA is <sup>providing notice and an opportunity to comment</sup> ~~reopening the comment period on the entire Bacterial Vaccine and Toxoids efficacy review document for 90 days.~~

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12-27-04

**DATES:** The final rule and final order published at 69 FR 255 (January 5, 2004), is withdrawn as of [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Astrid Szeto, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, 301-827-6210.



**AUTHORITY:** Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the final rule and final order published on January 5, 2004 (69 FR 255) is withdrawn.

Dated: 12.22.04  
December 22, 2004.

*Jeffrey Shuren*

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Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

**BILLING CODE 4160-01-S**

